IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

MARIA DALBOTTEN,

Plaintiff,

v.

C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

Case No. 1:20-cv-00034-SPW

ORDER ON DEFENDANTS' MOTION IN LIMINE TO EXCLUDE TESTIMONY AND EVIDENCE REGARDING FDA WARNING LETTER

Before the Court is Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion in Limine to Exclude Testimony and Evidence Regarding FDA Warning Letter (Doc. 187). Defendants seek to exclude items 1, 2, 4, 5, 6, 7, and 8 of a July 13, 2015, FDA Warning Letter issued to Bard regarding many issues with the manufacturing and quality assurance processes of several of Bard's IVC filters. (Doc. 188-1). Items 1 and 2 discuss alleged violations regarding the Recovery Cone device. Item 3 concerns alleged failures to receive, review, and evaluate complaints regarding several filters, including the G2 filter. Item 4 alleges that Bard failed to properly clean and scrub IVC filters before they left the facility. Items 5, 6, and 7 concern alleged issues regarding the Denali and Meridian filters. Finally, item 8 alleges that Bard submitted incomplete or missing information to the FDA, contrary to regulations.

Defendants assert that only Item 3 may be relevant and that ruling on its admissibility should be deferred until trial, when its relevance can be fully ascertained. (Doc. 188 at 4). Plaintiff argues that the motion should be denied as to Items 3, 4, 5, and 6, and reserved on the remaining issues. (Doc. 215 at 3-4). Plaintiff argues that the information regarding other filters is relevant because it demonstrates, through circumstantial evidence, that issues existed regarding the G2 filter's manufacturing process as well. Plaintiff agrees that she will not seek to introduce any part of the FDA Warning Letter without raising the issues outside the presence of the jury. (Doc. 215 at 12).

To be admissible, evidence must be relevant to one or more claims, meaning that it makes a fact at issue more or less likely to have occurred. Fed. R. Evid. 401. Even if evidence is relevant, it should be excluded if its relevance is substantially outweighed by its risk of confusing the jury as to the issues, among other things. Fed. R. Evid. 403.

Items 1, 2, 4, 5, 6, 7, and 8 are irrelevant and shall be excluded on that basis. Plaintiff was implanted with a G2 filter. Evidence regarding other filters, such as the Recovery Cone, Denali, or Meridian, do not make it more or less probable that those same issues existed regarding the G2. Items 4-6 do not, as Plaintiff claims, provide circumstantial evidence that Bard's G2 manufacturing process was also deficient. Circumstantial evidence in products liability cases in Montana includes

expert opinions regarding the probability that a defect caused the accident when the product is destroyed, eyewitness and user accounts regarding the accident, or evidence negating causes other than a defect. *See Brandenburger v. Toyota Motor Sales, U.S.A.*, 513 P.2d 268, 275. It does not include evidence that a similar product suffered from defects. Introducing evidence of improper manufacturing practices regarding other filters is not relevant evidence, and it is also inadmissible under Rule 403.

Items 1 and 2 relate to the Recovery Cone Removal System and are irrelevant.

Item 3(a) is likewise irrelevant because it concerns the Denali filter.

Item 4(a) concerns cleaning process failures, which are unrelated to Plaintiff's claims in this case.

Items 4(b), 5, 6, and 7 concern the Denali and Simon Nitinol filters and are irrelevant.

Item 8 relates to information provided by Bard to the FDA regarding Bard's complaint-handling process and is irrelevant to Plaintiff's claims.

Items 3(b) and 3(c) may be relevant depending on what evidence and testimony is produced at trial. Each sub-item includes alleged issues relating to the G2 filter and failures in the complaint investigation process. Therefore, evidence regarding sub-items 3(b) and 3(c) is potentially relevant. Accordingly, the Court

will defer ruling on the admissibility of sub-items 3(b) and 3(c) until trial, when the full scope of their relevance and potential for unfair prejudice, if any, can be fully considered. At that time, the Court shall also determine which, if any, redactions may be appropriate. The Court directs Plaintiff to raise the potential admissibility of Items 3(b) and 3(c) outside the hearing of the jury before mentioning the FDA Warning Letter to the jury.

Defendants' motion (Doc. 187) is GRANTED as to Items 1, 2, 3(a), 4, 5, 6, 7, and 8, and RESERVED as to Items 3(b) and 3(c).

DATED this 6th day of February, 2023.

Susan P. Watters

SUSAN P. WATTERS
United States District Judge